Louisiana Medicaid
Glucocorticoids, Oral

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred oral glucocorticoids
- Clinical authorization for deflazacort (Emflaza®)

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Non-Preferred Glucocorticoids, Oral (Except Emflaza®)

Approval Criteria for Initial and Reauthorization Requests

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: Up to 12 months based upon patient-specific factors and the condition being treated

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Deflazacort (Emflaza®)

Approval Criteria

- The recipient has a documented diagnosis of Duchenne muscular dystrophy (DMD); **AND**
- The recipient is 2 years of age or older on the date of the request; **AND**
- The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, a neurologist; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- **ONE** of the following:
    - The recipient had an inadequate response to a preferred prednisone / prednisolone product after 6 months or more of treatment (**medication name with begin and end dates of treatment are stated on the request**); **OR**
    - The recipient has a documented adverse reaction, intolerance, or contraindication to treatment with generic prednisone / prednisolone that is not expected to occur with the requested medication (explanation of why it is not expected to occur with the requested medication is required and **is stated on the request**); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recommended oral dosage of 0.9 mg/kg/day will not be exceeded; **AND**
    - The requested medication will not be given concurrently with live-attenuated or live vaccines; **AND**
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is receiving clinical benefit from deflazacort therapy, such as stabilization, maintenance, or improvement of muscle strength or pulmonary function, indicating a slowing of disease progression relative to the projected natural course of DMD.

Duration of reauthorization approval: 12 months

References

American Academy of Neurology. (2016). Practice Guideline Update Summary: Corticosteroid Treatment of Duchenne Muscular Dystrophy. https://n.neurology.org/content/86/5/465.full

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; https://www.clinicalkey.com/pharmacology/

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach, 10e* New York, NY: McGraw-Hill; https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861m

Emflaza (deflazacort) [package insert]. South Plainfield, NJ: PTC Therapeutics, Inc.; June 2021. http://hcp.emflaza.com/wp-content/themes/emflaza-hcp/pdf/prescribing-information.pdf

Revision / Date	**Implementation Date**
Policy created	January 2020
Policy implemented and combined with Oral Glucocorticoid non-preferred criteria document / May 2020	May 2020
Formatting changes / April 2021	July 2021
Updated references; formatting changes / September 2021	January 2022